

Food and Drug Administration, HHS

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(m) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH are authorized to impose sanctions under section 354(h)(2) of the PHS Act (42 U.S.C. 263b(h)(2)).

(n) The following officials are authorized to develop and implement the procedures for determining when and how to impose sanctions as provided by section 354(h)(3) of the PHS Act (42 U.S.C. 263b(h)(3)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(o) The following officials are authorized to suspend or revoke individual facility certificates under section 354(i)(1) and (i)(2) of the PHS Act (42 U.S.C. 263b(i)(1) and (i)(2)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(p) The following officials are authorized under section 354(i)(3) of the PHS Act (42 U.S.C. 263b(i)(3)) to ensure that no person who owned or operated a facility at the time the cause of revocation occurred may, within 2 years of the revocation of the certificate, own or operate a mammography facility:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(q) The following officials are authorized to compile and make available to physicians and the general public information determined to be useful in evaluating the performance of mammography facilities as provided by section 354(l) of the PHS Act (42 U.S.C. 263b(l)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(r) The following officials are authorized to ensure that appropriate Federal agencies are consulted in the development of standards, regulations, evaluations, procedures for compliance and oversight as provided by section 354(o) of the PHS Act (42 U.S.C. 263b(o)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(s) The following officials may authorize a State to carry out certification program requirements and implement quality standards under section 354(q)(1) and (q)(2) of the PHS Act (42 U.S.C. 263b(g)(1) and (g)(2)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(t) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH are authorized, after providing notice and opportunity for corrective action, to withdraw the approval of a State's authority to carry out certification requirements and implement quality standards under section 354(q)(4) of the PHS Act (42 U.S.C. 263b(g)(4)).

(u) These officials may not further redelegate these authorities.

Subpart M—Organization

§ 5.1100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER.¹

Office of the Chief Counsel.

Office of Equal Opportunity.

Office of the Administrative Law Judge.

Office of the Senior Associate Commissioner.

Office of Executive Secretariat.

Office of Public Affairs.

Office of the Ombudsman.

¹Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

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Office of Orphan Products Development.
Office of Internal Affairs.
Office of Executive Operations.
Office of Science Coordination and Communication.
Office of Human Research Trials.
Office of International and Constituent Relations.
Office of International Programs.
Office of Consumer Affairs.
Office of Women's Health.
Office of Special Health Issues.
Office of Policy, Planning, and Legislation.
Office of Policy.
Office of Planning.
Office of Legislation.
Office of Management and Systems.
Office of Human Resources and Management Services.
Office of Information Resources Management.
Office of Financial Management.
Office of Facilities, Acquisitions, and Central Services.²
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH.³
Office of the Center Director.
Scientific Advisors and Consultants Staff.
Equal Employment Opportunity and Workforce Diversity Staff.
Quality Assurance Staff.
Regulations and Policy Staff.
Veterinary Services Staff.
Office of Management.
Regulatory Information Management Staff.
Division of Planning, Evaluation, and Budget.
Division of Management Services.
Office of Information Technology Management.
Division of Information Technology Operations.
Division of Information Technology Development.

Division of Information Technology Infrastructure.
Office of Compliance and Biologics Quality.
Division of Case Management.
Division of Manufacturing and Product Quality.
Division of Inspections and Surveillance.
Office of Blood Research and Review.
Human Tissue Staff.
Policy and Publications Staff.
Division of Emerging and Transfusion Transmitted Diseases.
Division of Hematology.
Division of Blood Applications.
Office of Therapeutics Research and Review.
Division of Cellular and Gene Therapies.
Division of Therapeutic Proteins.
Division of Monoclonal Antibodies.
Division of Clinical Trial Design and Analysis.
Division of Application Review and Policy.
Office of Vaccines Research and Review.
Division of Bacterial, Parasitic, and Allergenic Products.
Division of Viral Products.
Division of Vaccines and Related Products Applications.
Office of Communication, Training, and Manufacturers Assistance.
Division of Disclosure and Oversight Management.
Division of Manufacturers Assistance and Training.
Division of Communication and Consumer Affairs.
Office of Biostatistics and Epidemiology.
Division of Biostatistics.
Division of Epidemiology.
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION.⁴
Office of the Center Director.
Food Safety Initiatives Staff.
Office of Science
Quality Assurance Staff.

²Mailing address: 5630 Fishers Lane, Rockville, MD 20857.

³Mailing address: 1401 Rockville Pike, Rockville, MD 20852-1448.

⁴Mailing address: 5100 Paint Branch Pkwy., College Park, MD 20740.

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CFSAN Staff College.
Microbial Research and Risk Assessment Staff.
JIFSAN Liaison Staff.
CFSAN Food Advisory Committee Staff.
Office of Applied Research and Safety Assessment.
Muirkirk Technical Operations Staff.
Division of Molecular Biology.
Division of Virulence Assessment.
Division of Toxicology and Nutritional Product Studies.
Division of In Vitro and Biochemical Toxicology.
Office of Regulations and Policy.
Regulations Coordination Staff.
Office of Constituent Operations.
Consumer Education Staff.
Industry Activities Staff.
International Activities Staff.
Office of Management Systems.
Safety Management Systems.
Division of Information Resources Management.
Division of Planning and Financial Resources Management.
Division of Management Operations.
Division of Administrative Services Management.
Office of Operations.
Equal Employment Opportunity Staff.
Executive Operations Staff.
Office of Cosmetics and Colors.
Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.
Office of Nutritional Products, Labeling and Dietary Supplements.
Division of Compliance and Enforcement.
Division of Standards and Labeling Regulations.
Division of Nutrition Science Policy.
Office of Premarket Approval.
Division of Product Policy.
Division of Petition Control.
Division of Health Effects Evaluation.
Division of Product Manufacture and Use.

Office of Plant and Dairy Foods and Beverages.
Division of Pesticides and Industrial Chemicals.
Division of Natural Products.
Division of Food Processing and Packaging.
Division of Plant Product Safety.
Division of Dairy and Egg Safety.
Division of Risk Assessment.
Division of Microbiological Studies.
Office of Seafood.
Division of Special Programs.
Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.
Office of Field Programs.
Division of Enforcement and Programs.
Division of HACCP Programs.
Division of Cooperative Programs.
Office of Scientific Analysis and Support.
Division of General Scientific Support.
Division of Mathematics.
Division of Market Studies.
CENTER FOR DRUG EVALUATION AND RESEARCH.¹
Office of the Center Director.
Equal Employment Opportunity Staff.
Executive Operations Staff.
Office of Regulatory Policy.
Division of Regulatory Policy I.
Division of Regulatory Policy II.
Division of Information Disclosure Policy.
*Office of Management.*¹
Strategic Planning Staff.¹
*Division of Management and Budget.*⁵
Division of Management Services.¹
*Office of Training and Communication.*¹
Medwatch Staff.
Division of Library and Information Services.
Division of Training and Development.
Division of Public Affairs.
Division of Drug Information.

⁵Mailing address: 7500 Standish Pl., Rockville, MD 20855.

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Office of Compliance.⁶
Division of Manufacturing and Product Quality.
Division of Prescription Drug Compliance and Surveillance.
Division of Labeling and Non-Prescription Drug Compliance.
*Office of Information Technology.*¹
Quality Assurance Staff.
Technology Support Services Staff.
Division of Data Management and Services.
Division of Applications Development and Services.
Division of Infrastructure Management and Services.
*Office of Medical Policy.*¹
Division of Drug Marketing, Advertising and Communication.¹
Division of Scientific Investigations.⁵
*Office of Review Management.*¹
Advisors and Consultants Staff.²
*Office of Drug Evaluation I.*¹
Division of Cardio-Renal Drug Products.
Division of Neuropharmacological Drug Products.
Division of Oncology Drug Products.
*Office of Drug Evaluation II.*¹
Division of Metabolic and Endocrine Drug Products.
Division of Pulmonary and Allergy Drug Products.
Division of Anesthetic, Critical Care and Addiction Drug Products.
*Office of Drug Evaluation III.*¹
Division of Gastrointestinal and Coagulation Drug Products.
Division of Medical Imaging and Radiopharmaceutical Drug Products.
Division of Reproductive and Urologic Drug Products.
*Office of Drug Evaluation IV.*¹
Division of Anti-Infective Drug Products.
Division of Anti-Viral Drug Products.
Division of Special Pathogen and Immunologic Drug Products.
*Office of Drug Evaluation V.*¹

⁶Mailing address: 7520 Standish Pl., Rockville, MD 20855.

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Division of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products.
Division of Dermatologic and Dental Drug Products.
Division of Over-The-Counter Drug Products.
*Office of Biostatistics.*¹
Quantitative Methods Research Staff.
Division of Biometrics I.
Division of Biometrics II.
Division of Biometrics III.
*Office of Post-Marketing Drug Risk Assessment.*¹
Extramural Programs Staff.
Information Technology Staff.
Division of Drug Risk Evaluation I.
Division of Drug Risk Evaluation II.
*Office of Pharmaceutical Science.*¹
Quality Implementation Staff.¹
Operations Staff.¹
Office of Clinical Pharmacology and Biopharmaceutics.
Pharmacometrics Staff.
Division of Pharmaceutical Evaluation I.¹
Division of Pharmaceutical Evaluation II.¹
Division of Pharmaceutical Evaluation III.¹
*Office of Generic Drugs.*⁶
Division of Bioequivalence.
Division of Chemistry I.
Division of Chemistry II.
Division of Labeling and Program Support.
*Office of New Drug Chemistry.*¹
Division of New Drug Chemistry I.¹
Division of New Drug Chemistry II.¹
Division of New Drug Chemistry III.¹
*Office of Testing and Research.*¹
Informatics and Computational Safety Analysis Staff.
Laboratory of Clinical Pharmacology.¹
Division of Applied Pharmacology Research.⁷
Division of Pharmaceutical Analysis.⁸

⁷Mailing address: 8301 Muirkirk Rd., Laurel, MD 20708.

⁸Mailing address: 1114 Market St., St. Louis, MO 63101.

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Division of Product Quality Research.¹
OFFICE OF REGULATORY AFFAIRS.¹
Equal Employment Opportunity Staff.
Office of Resource Management.
Strategic Initiatives Staff.
Division of Planning, Evaluation, and Management.
Division of Information Systems.
Division of Human Resource Development.
Division of Management Operations.
Division of Personnel Operations.
Office of Enforcement.
Division of Compliance Management and Operations.
Division of Compliance Policy.
Division of Compliance Information and Quality Assurance.
Office of Regional Operations.
Division of Federal-State Relations.
Division of Field Science.
Division of Emergency and Investigational Operations.
Division of Import Operations and Policy.
Office of Criminal Investigations.
Mid-Atlantic Area Office.⁹
Midwest Area Office.¹⁰
Northeast Area Office.¹¹
Pacific Area Office.¹²
Southeast Area Office.¹³
Southwest Area Office.¹⁴
CENTER FOR VETERINARY MEDICINE.¹⁵
Office of the Center Director.
Office of Management and Communications.
Administrative Staff.
Communications Staff.

⁹Mailing address: 900 U.S. Customhouse, Second Chestnut St., Philadelphia, PA 19106.

¹⁰Mailing address: 901 Warrenville Rd., suite 360, Lisle, IL 60532.

¹¹Mailing address: 158-15 Liberty Ave., Jamaica, NY 11433.

¹²Mailing address: 13301 Clay St., Oakland CA 94512.

¹³Mailing address: 60 Eighth St. NE, Atlanta, GA 30309.

¹⁴Mailing address: 7920 Elmbrook Rd., Dallas, TX 75247.

¹⁵Mailing address: 7500 Standish Pl., MPN-2, Rockville, MD 20855.

Information Resources Management Staff.

Office of New Animal Drug Evaluation.

Division of Therapeutic Drugs for Food Animals.

Division of Biometrics and Production Drugs

Division of Therapeutic Drugs for Nonfood Animals.

Division of Manufacturing Technologies.

Division of Human Food Safety.

Office of Surveillance and Compliance.

Division of Surveillance.

Division of Animal Feeds.

Division of Compliance.

Division of Epidemiology.

Office of Research.

Administrative Staff.

Division of Residue Chemistry.

Division of Animal Research.

Division of Animal and Food Microbiology.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.¹⁶

Office of the Center Director.

Equal Employment Opportunity Staff.

Office of Systems and Management.

Integrity Committee and Conference Management Staff.

Division of Management Operations.

Division of Information Dissemination.

Division of Information Technology Management.

Division of Planning, Analysis and Finance.

Office of Compliance.

Promotion and Advertising Policy Staff.

Division of Bioresearch Monitoring.

Division of Program Operations.

Division of Enforcement I.

Division of Enforcement II.

Division of Enforcement III.

Office of Device Evaluation.

Program Management Staff.

Program Operations Staff.

Division of Cardiovascular and Respiratory Devices.

¹⁶Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

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Division of Reproductive, Abdominal and Radiological Devices.

Division of General, Restorative and Neurological Devices.

Division of Clinical Laboratory Devices.

Division of Ophthalmic, Ear, Nose, and Throat Devices.

Division of Dental, Infection Control, and General Hospital Devices.

Office of Science and Technology.

Division of Mechanics and Materials Science.

Division of Life Sciences.

Division of Physical Sciences.

Division of Electronics and Computer Sciences.

Division of Management Information and Support Services.

Office of Health and Industry Programs.

Program Operations Staff.

Regulations Staff.

Staff College.

Division of Device User Programs and Systems Analysis.

Division of Small Manufacturers Assistance.

Division of Mammography Quality and Radiation Programs.

Division of Communication Media.

Office of Surveillance and Biometrics.

Issues Management Staff.

Division of Biostatistics.

Division of Postmarket Surveillance.

Division of Surveillance Systems.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH.¹⁷

Office of the Center Director.

Environmental Health and Program Assurance Staff.

Office of Research.

Technology Advancement Staff.

Division of Biochemical Toxicology.

Division of Genetic and Reproductive Toxicology.

Division of Biometry and Risk Assessment.

Division of Microbiology.

Division of Chemistry.

¹⁷Mailing address: 3900 NCTR Dr., Jefferson, AR 72079.

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Division of Neurotoxicology.

Division of Veterinary Services.

Division of Molecular Epidemiology.

Office of Management.

Office of Management Services.

Division of Facilities, Engineering and Maintenance.

Division of Administrative Services.

Division of Contracts and Acquisitions.

Office of Planning, Finance and Information Technology.

Division of Planning.

Division of Financial Management.

Division of Information Technology.

[66 FR 30993, June 8, 2001, as amended at 66 FR 56035, Nov. 6, 2001]

§ 5.1105 Chief Counsel, Food and Drug Administration.

The Office of the Chief Counsel's mailing address is 5600 Fishers Lane, rm. 6–57, Rockville, MD 20857.

§ 5.1110 Food and Drug Administration Public Information Offices.

(a) *Division of Dockets Management (HFA–305).* The Division of Dockets Management Public Room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. Telephone: 301–827–6860.

(b) *Freedom of Information Staff (HFI–35).* The Freedom of Information Public Room is located in rm. 12A–30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6567.

(c) *Press Relations Staff (HFI–40).* Press Offices are located in rm. 15–05, Parklawn Bldg, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6242; and in rm. 3807, FB–8, 5100 Paint Branch Pkwy., College Park, MD 20740. Telephone 202–205–4144.

[66 FR 30993, June 8, 2001, as amended at 66 FR 56035, Nov. 6, 2001]

§ 5.1115 Field structure.

NORTHEAST REGION

Regional Field Office: 158–15 Liberty Ave., Jamaica, NY 11433.

Northeast Regional Laboratory: 158–15 Liberty Ave., Jamaica, NY 11433.

New York District Office: 158–15 Liberty Ave., Jamaica, NY 11433.